

Amendments to the Drawings:

The attached (18) sheets of drawings include a resubmission of all 20 figures in the application. Sheet 1, which includes **FIGS. 1 and 1a**, replaces the original Sheet 1, including original **FIGS. 1 and 1a**. Sheet 2, which includes **FIGS. 2, 2a, 2b, 2c and 2d** replaces the original Sheet 2, including original **FIGS. 2, 2a, 2b, 2c and 2d**. Sheet 3, which includes **FIGS. 3, 3a, 4 and 4a**, replaces the original Sheet 3, including original **FIGS. 3, 3a, 4 and 4a**. Sheet 4, which includes **FIGS. 5 and 6, and 6a-6d**, replaces the original Sheet 4, including original **FIGS. 5 and 6 and 6a-6d**. Sheet 5, which includes **FIGS. 7 and 7a-7c**, replaces the original Sheet 5, including original **FIGS. 7 and 7a-c**.

Sheet 6, which includes **FIGS. 8a-8c**, replaces the original Sheet 6, including original **FIGS. 8a-8c**. Sheet 7, which includes **FIGS. 8d-8e and 12b**, replaces the original Sheet 7, including original **FIGS. 8d-8e and 12b**. Sheet 8, which includes **FIGS. 9 and 10a-10c**, replaces the original Sheet 8, including original **FIGS. 9 and 10a-10c**. Sheet 9, which includes **FIGS. 11a-11d**, replaces the original Sheet 9, including original **FIGS. 11a-11d**. Sheet 10, which includes **FIGS. 11e, 12 and 12a**, replaces the original Sheet 10, including original **FIGS. 11a, 12 and 12a**.

Sheet 11, which includes **FIGS. 13a-13d**, replaces the original Sheet 11, including original **FIGS. 13a-13d**. Sheet 12, which includes **FIGS. 13e-13g and 14a**, replaces the original Sheet 12, including original **FIGS. 13e-13g and 14a**. Sheet 13, which includes **FIGS. 14b-14c and 15**, replaces the original Sheet 13, including original **FIGS. 14b-14c and 15**. Sheet 14, which includes **FIGS. 16 and 16a-16c**, replaces the original Sheet 14, including original **FIGS. 16 and 16a-16c**. Sheet 15, which includes **FIGS. 17a-17e**, replaces the original Sheet 15, including original **FIGS. 17a-17e**. Sheet 16, which includes **FIGS. 18a-18e**, replaces the original Sheet 16, including original **FIGS. 18a-18e**. Sheet 17, which includes **FIGS. 18f-18j**, replaces the original Sheet 17, including original **FIGS. 18f-18j**. Sheet 18, which includes **FIGS. 19a, 19b and 20**, replaces the original Sheet 18, including original **FIGS. 19a, 19b and 20**.

Attachment: Replacement Sheets 1-18

Remarks

The Official Action mailed September 21, 2009 has been carefully considered. Reconsideration and allowance of the subject application, as amended, are respectfully requested.

Claims 40-75 remain pending in the application. Claims 74 and 75 were withdrawn due to an Election/Restriction requirement in a telephone conference with the writer on September 10, 2009. Claim 64 has been cancelled.

Independent claims 40 and 71 have been amended to recite that the support structure has a primary and a secondary shape with the primary shape having a greater length-to-width ratio than the secondary shape. Support may be found in paragraph [0040] of the published U.S. application which recites “[a]lternatively or in addition to the positioning system described above, it is possible for such a system to have an advancing element, an auxiliary structure having a great length-to-width ratio along an axis in a first operating state (primary shape) while having a smaller length-to-width ratio along said axis in a second operating state (secondary shape) for aiding the deployment of the proximal end of the support structure, and at least one connection device for connecting the proximal end of the implantable device and the distal end of the auxiliary structure.” Accordingly, no new matter has been entered.

Claim 40 has also been amended to recite that the single wire-like element has two ends. Support may be found in original claim 51. No new matter has been entered.

A new set of drawings (Replacement Sheets 1-18, **FIGS. 1-20**) are included with this paper in response to the request that a corrected set of drawings be provided due to the poor quality of the originals. No new matter has been entered.

Claims 40-73 were rejected under 35 U.S.C. § 112, second paragraph, on the grounds of being indefinite. Claim 40 has had the phrase “etc.” cancelled and some punctuation adjusted to clarify what is being claimed. Claims 40 and 41 have been amended to recite an opening between “two” walls. See paragraph [0020] of the published application for support. Claim 46 has been amended to recite the “area” of application within said body. See paragraph [0020] of the published application for support. No new matter has been entered.

Claim 48 has been amended to recite “the concentration and/or thickness of said wire-like element of the support structure is different from portion to portion.” See paragraph [0024] of the published application for support. Claim 49 has been amended to recite “The implantable device as claimed in claim 48, wherein partial areas of the support structure are formed from a wire-like element having different diameters, or wherein partially different diameters of the wire-like element of the support structure are formed by provision of several wires. See paragraph [0024] of the published application for support. No new matter has been entered.

Claim 50 has been amended to replace the word “material” with the phrase “wire-like element”. Claim 51 has been amended to recite that “the wire-like element includes two ends” to provide proper antecedent basis. This also provides proper antecedent basis for claim 57. Claim 51 has also been amended to recite that the support structure has “distal or proximate ends” to provide proper antecedent basis for “the end” in claims 52 and 53. See paragraph [0018] of the published application for support. Claim 55 has been amended to recite “the individual parts of the two-part or multi-part unit of the support structure are designed uniformly, corresponding to one another or differing from one another.” See paragraph [0027] of the published application for support. No new matter has been entered.

Claim 56 has been amended to cancel the language “or basic coil shape” and “primary shape” has been introduced into independent claim 40. See paragraph [0031] for support. Claim 59, 61, 65 and 66 were amended to cancel the phrase “in particular”. Claim 61 was amended to remove the references to specific polymers. Claim 62 has been amended to recite “said” edge are referring back to claim 40. Claim 68 has been amended to recite “said” retaining wire referring back to claim 67. No new matter has been entered.

Claims 40-73 have been amended to recite “wherein” in place of “characterized in that”.

Claim 73 has been amended to recite “wherein the at least one retaining wire is threaded or can be threaded through one or more loops or hoops of said intercoiled support structure at said proximal end and/or said distal end of the auxiliary structure. Support may be found at paragraph [0025] which recites “[t]he support structure is formed from

only one wire-like element, the end of the proximal portion preferably has one or more hoops or loops which are arranged alongside one another and/or interlocked and/or interlaced.” No new matter has been entered.

Turning to the rejections, claims 40-59 and 63-66 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Amplatz et al. (US 5,944,737). Amplatz et al. appears to be directed at a collapsible medical device comprising a tubular metal *fabric* of woven metal *strands*, the device collapsible for delivery into a patient’s body. The reference appears to be directed at a wire braid (woven strands). There is no reference to a support structure comprising a single wire element having two ends that has been coiled, intertwined or interwoven (with itself). See amended claim 40. The Office Action cites to **FIG. 5** and column 5, lines 3-4 for the proposition that the cited reference discloses a single wire element.

However, **FIG. 5** and column 5, lines 3-4 when read in their entirety are not believed to support such an interpretation of the Amplatz reference. Specifically, **FIG. 5** is disclosed to be a tubular braid (column 10, lines 9-16). Column 5, lines 3-4 disclose that the device is formed from a continuous tubular metal “*fabric*” where the fabric is “*formed from a plurality of wire strands.*” This, of course, is dissimilar and not a teaching of the subject matter in amended claim 40 with respect to the feature of a single wire element with two ends. To further emphasize the point, Amplatz at column 10 lines 21-23 recites “[t]he ends **26** and **28** of the tubular braided metal fabric device **10** are welded or clamped together to prevent fraying.”

Furthermore, Amplatz recites at column 3 lines 19-26 “[w]hen forming these intravascular devices from a resilient metal fabric *a plurality of resilient strands or wires are provided*, with the metal fabric being formed by braiding the resilient strands to create a resilient material. This braided fabric is then deformed to generally conform to a molding surface of a molding element and the braided fabric is heat treated in contact with the surface of the molding element at an elevated temperature.” (Emphasis added.) Accordingly, a single wire-like element does not appear to be anticipated and or suggested by Amplatz.

Claims 60-62 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Amplatz et al. (US 5,944,737) in view of Gainor et al. (US 2002/0169475). The

deficiencies of Amplatz are discussed above. Gainor et al. appears to be directed at a septal defect closure device having a first occluding disk having a first flexible membrane attached to a first frame and a second occluding disk having a second flexible membrane attached to a second frame. This membrane appears to be a *woven fabric*. The reference appears to be silent regarding a support structure comprising a single wire element that has been coiled, intertwined or interwoven (with itself). It is submitted that Gainor et al. does not make up for the deficiencies of Amplatz as at least one feature (single-wire construction) is missing from the combination of references. Further, claims 60-62 depend indirectly from amended claim 40 and are believed to be similarly distinguished.

Claims 67-73 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Amplatz et al. (US 5,944,737) in view of Shaw et al. (US 6,171,329). The deficiencies of Amplatz are discussed above. Shaw et al. appears to be directed at a positioning system including a self-expanding device for sealing a defect in a wall, the device having a helical shaped *frame* formed from an elastic wire *which is attached to a laminated membrane* having at least one non-circular eyelet. The membrane may be formed of expanded PTFE and attached to the end of the wire to be expanded after being advanced out of a catheter. This reference does not teach or suggest that the membrane be “formed from a single wire-like element by intercoiling and/or intertwining and/or interweaving in the manner of a tissue and/or scrim and/or net structure.” In Shaw et al., a wire only forms the periphery of the device to support the elastic membrane.

The Office Action indicates that the positioning system of Shaw et al. includes a retaining wire **96** and an extraction wire **104**. This is respectfully believed to be incorrect. Shaw et al. at column 11 lines 34-53 identifies **96** as a suture and at column lines 11-19 identifies **104** as the distal end of the closure device **68** and not an extraction wire.

It is submitted that Shaw et al. does not provide a retaining wire but instead a combination of tissue and a wire **50** wherein wire **50** is more or less a linking element which remains at the helical closure device **68** after providing the closure device in a defect opening.

Furthermore, Shaw et al. does not teach or disclose the threading of one or more loops at the end of the proximal position of the implantable device to retain the device or for being able to separate the retaining device from the implantable device after it has

been implanted. **FIG. 12A**, referenced at page 9 of the Office Action as illustrating where a retaining loop is formed, does not appear to illustrate a loop. The description of **FIG. 12A** at column 11 lines 34-52 appears to be directed at a suture retrieval means where the suture is pre-threaded through the proximal eyelet. The eyelet is part of the helical wire frame that supports the laminated membrane. In the present invention, the implantable device is formed from a single wire-like element, having two ends, by intercoiling and/or intertwining and/or interweaving such wire.

In other words, the implantable device of the present invention is a coiled wire and it may be looped within itself and not require a separate eyelet formed into a frame as disclosed by Shaw et al. See amended claim 73.

Claims 67-73 depend directly or indirectly from amended claim 40 and are believed to be similarly distinguished.

The present invention discloses and claims an implantable device in the form of an advancing element including a support structure formed from a single wire-like element, having two ends, by intercoiling and/or intertwining and/or interweaving. The cited art taken separately or in combination do not teach or suggest such features.

Having dealt with all the objections raised by the Examiner, it is respectfully submitted that the present application, as amended, is in condition for allowance. Thus, early allowance is earnestly solicited.

If the Examiner desires personal contact for further disposition of this case, the Examiner is invited to call the undersigned Attorney at 603.668.6560.

In the event there are any fees due, please charge them to our Deposit Account No. 50-2121.

Respectfully submitted,

By: /Steven J. Grossman/
Steven J. Grossman, Ph.D.
Reg. No. 35,001